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Novo Nordisk, Inc. and Novo Nordisk A/S

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVO NORDISK INC. and NOVO NORDISK A/S, Plaintiffs, v. MYLAN PHARMACEUTICALS INC., Defendant.	Civil Action No. _____

COMPLAINT

Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S ("Novo Nordisk"), by their attorneys Gibson, Dunn & Crutcher LLP, for their Complaint against Mylan Pharmaceuticals Inc. ("Mylan"), hereby allege:

NATURE OF THE ACTION

1. This is a civil action for the infringement of United States Patent No. 6,677,358 ("the '358 patent"), pursuant to the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

THE PARTIES

2. Plaintiff Novo Nordisk Inc. is a Delaware corporation having its principal place of business at 100 College Road West, Princeton, New Jersey.

3. Plaintiff Novo Nordisk A/S is a corporation organized and existing under the laws of the Kingdom of Denmark and having its principal place of business at Novo Allé, 2880 Bagsværd, Denmark.

4. Upon information and belief, Defendant Mylan is a corporation organized and existing under the laws of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia.

5. Upon information and belief, Defendant Mylan is registered to do business in New Jersey and has appointed Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey 08628 as its registered agent in New Jersey for the receipt of service of process.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and 35 U.S.C. § 271(e)(2).

7. This Court has personal jurisdiction over Mylan by virtue of, *inter alia*, Mylan's continuous and systematic contacts with New Jersey, its sale of prescription drugs in New Jersey, its registration of prescription drug products in the *New Jersey Generic Formulary* of the New Jersey Department of Health and Senior Services, its consent to being sued in New Jersey, as

evidenced by its registration to do business in New Jersey and its appointment of a registered agent in New Jersey, and its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in New Jersey.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT

9. On January 13, 2004, the '358 patent, entitled "NIDDM Regimen," was duly and legally issued by the United States Patent and Trademark Office to Novo Nordisk A/S as assignee. Since that time, Novo Nordisk A/S has been, and continues to be, the sole owner of the '358 patent. A copy of the '358 patent is attached hereto and incorporated herein as Exhibit A.

10. The '358 patent is directed to and claims a pharmaceutical composition which includes repaglinide, metformin and a carrier (claim 1) in the form of a tablet (claim 2) or a capsule (claim 3); a method for treating non-insulin dependent diabetes mellitus ("NIDDM") by administering repaglinide and metformin to a patient in need of treatment (claim 4) and a kit that includes repaglinide and metformin (claim 5).

PRANDIN®

11. Novo Nordisk Inc. holds an approved New Drug Application ("Novo Nordisk's NDA") for repaglinide, which it sells under the registered trademark PRANDIN®.

12. PRANDIN® was approved on December 22, 1997, by the U.S. Food and Drug Administration ("FDA") for combination therapy of NIDDM with metformin. Novo Nordisk Inc. is the holder of this approval.

13. The listing for PRANDIN® in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book") includes Novo Nordisk A/S's '358 patent.

ACTS GIVING RISE TO THIS CIVIL ACTION

14. Upon information and belief, Mylan submitted Abbreviated New Drug Application ("ANDA") No. 90-252 to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of generic 0.5, 1, and 2 mg oral repaglinide tablets ("Mylan's Repaglinide") prior to the expiration of the '358 patent.

15. Upon information and belief, ANDA No. 90-252 refers to and relies upon Novo Nordisk's NDA for PRANDIN® and purports to contain data showing bioequivalence of Mylan's Repaglinide with PRANDIN®.

16. On April 7, 2009, Novo Nordisk Inc. received from Mylan a letter dated April 6, 2009, stating that ANDA No. 90-252 had been amended to include an allegation under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") that claims 1-3 and 5 of the '358 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Mylan's Repaglinide.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,677,358

17. Novo Nordisk hereby realleges and incorporates by reference the allegations of paragraphs 1-16 of this Complaint.

18. Mylan's submission on ANDA 90-252 to the FDA with a Paragraph IV certification regarding the '358 patent, with the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of repaglinide before the expiration of the '358 patent, constitutes infringement of the '358 patent under 35 U.S.C. § 271(e)(2)(A).

19. Upon information and belief, upon approval of ANDA No. 90-252, Mylan will directly and/or indirectly infringe the '358 patent under 35 U.S.C. § 271(a), (b), and (c).

20. Mylan's infringement has been willful and deliberate in disregard of Novo Nordisk's lawful rights under the '358 patent, thus rendering this case exceptional within the meaning of 35 U.S.C. § 285.

21. The acts of infringement set forth above will cause Novo Nordisk irreparable harm for which it has no adequate remedy at law, and will continue unless the FDA's approval of ANDA No. 90-252 is stayed until the expiration of the '358 patent, and unless Mylan is preliminarily and permanently enjoined by this Court.

WHEREFORE, Novo Nordisk prays that this Court:

a. enter a judgment that Mylan has infringed the '358 patent under 35 U.S.C. § 271(e)(2)(A);

b. stay FDA approval of Mylan's ANDA for at least thirty months, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii);

c. order that, pursuant to 35 U.S.C. § 271(e)(4)(A), any effective date of any approval of Mylan's Repaglinide shall be a date not earlier than the date of the expiration of the '358 patent, including any extensions;

d. enter a judgment that Mylan's manufacture, use, offer for sale, or sale in the United States or importation into the United States of the repaglinide products that are the subject of ANDA No. 90-252 will infringe and actively induce the infringement of the '358 patent under 35 U.S.C. § 271(a) and (b);enter a judgment that Mylan's infringement and active inducement of infringement under 35 U.S.C. § 271(a) and (b) by Mylan's manufacture, use, offer

for sale, or sale in the United States, or importation into the United States of the repaglinide products that are the subject of ANDA No. 90-252 will be willful;

e. enter a judgment that Mylan's activities have made this an exceptional case under 35 U.S.C. § 285;

f. preliminarily and permanently enjoin and restrain Mylan and its respective officers, directors, agents, servants, employees, and attorneys, and those in active concert or participation with them, from the manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the repaglinide products that are the subject of ANDA No. 90-252 and any other product that infringes or induces infringement of the '358 patent, prior to the expiration of the '358 patent, including any extensions;

g. grant Novo Nordisk compensatory damages in an amount to be determined at trial including both prejudgment and postjudgment interest if Mylan commercially manufactures, uses, offers for sale, or sells in the United States, or imports into the United States, the repaglinide products that are the subject of ANDA 90-252, or any other product that infringes or induces infringement of the '358 patent, prior to the expiration of the '358 patent, including any extensions;

h. award Novo Nordisk treble damages;

i. award Novo Nordisk its costs, expenses, and attorney fees that it incurs in prosecuting this action; and

j. grant Novo Nordisk any such other and further relief as the Court may deem just and proper.

Dated: May 20, 2009

Respectfully submitted,

/s/ Marshall R. King
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